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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,331	10/17/2003	David T. Bach		2309

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Clifford Kraft
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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/688,331

Applicant(s)

BACH ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/30/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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1. Claims 1-14 and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and incomplete since there is no structural cooperation recited among the components of the apparatus. In other words, the physical and structural relationships among the recited components of the apparatus are not clear. Where is the cell detection system located in relation to the fluid inlet port? Where is the sorting gate located in relation to the fluid inlet port and the cell collection port or waste port? See this same problem in claim 8.

In claim 19, the phrase "said optical system" lacks antecedent basis since independent claim 15 recites an optical detection region.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Diessel et al.

Diessel et al teach of a method and apparatus for sorting biological cells. The method comprises flowing a cell stream 2 through a feed inlet 1, which leads to individual sorting modules 4. After sorting, the streams of positive and negative channels from each sorting module unite to form a collecting channel 5 for positive cells and a collecting channel 6 for negative cells. Each sorting module comprises a main channel 3 with an optical detection system located there along. The optical detection system comprises both a light scatter sensor 9 and a fluorescence sensor 10. Downstream of the optical detection system is located a switch unit 11 with a sorting actuator 12. The cells to be sorted are classified with the scattered light sensor and the fluorescence light sensor according to their size and other parameters. Light is introduced into the channel 3 via light guides from an illumination device 13 arranged outside the channel. Detectors 9 and 10 are connected via lines 14 to an evaluation and control electronics 15, which is connected via line 16 to the sorting actuator 12. Diessel et al teach that the main channel 3 with the switch unit 11, the optical sensors 9 and 10, the sorting actuator 12 and the evaluation and control electronics 15 are integrated into a monolithic silicon chip. The sorting actuator 12 brings about a diversion of cell flow to either a cell outlet channel 19 or a waste channel 20 depending upon the signal from the optical sensors sent to the control electronics 15. Diessel et al teach that many different actuator sorting principles are suitable for use in the device. One of the actuator principles that can be used is a magnetostrictive actuator in the form of flexible tongues in the channel 3 at the location of the two channels 19, 20. The magnetostrictive tongues can bend under the influence of an external magnetic field due to magnetostrictive forces. This causes a narrowing of the cross-section of the channel 20 that causes the cell stream

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to flow out of the channel 19. See Figures 1-2, 3A, 3B, lines 44-67 in column 3, lines 1-57 in column 4 and lines 2-5 in column 5 of Diessel et al.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diessel et al in view of Wada et al. For a teaching of Diessel et al, see previous paragraphs in this Office action. Diessel et al fail to teach of a pump and vacuum for causing the cell stream to flow through the channels 3, 19 or 20, and fail to teach that the optical detection system can comprise a photomultiplier or a diode array.

Wada et al teach of a microfluidic device for sorting cells that comprises a channel network in fluid communication with multiple wells and reservoirs. The channel network includes a main analysis channel and one or more side channels connecting the reservoirs to the main channel. Cells are flowed through the side channels and into the main channel by a flow controller in the form of one or more constant or variable pressure or vacuum sources. Wada et

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al teach that the flow controller can be a positive displacement pump, a peristaltic pump or another type of common pump. In addition, the flow controller can be a vacuum source for drawing fluid through the channels of the device. An optical detection system located along the length of the main channel serves to detect and analyze cells flowing there through. The optical detection system can measure light scattering or fluorescence by means of a photodiode or a photomultiplier. In addition, multiple optical detectors can be used for detecting different signals during operation of the system. See paragraph nos. 0034-0035, 0038, 0040, 0041, and 0055-0057 of Wada et al.

Based upon the combination of Diessel et al and Wada et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use pumps or a vacuum to move the cell-containing fluid through the channels in the device taught by Diessel et al since Wada et al teach that pumps or a vacuum are common flow controllers used to flow a cell-containing stream to be sorted through a channel network, such as that included in the device of Diessel et al. It also would have been obvious to one of ordinary skill in the art to use one or more diodes or photomultipliers as the optical detection system in the device taught by Diessel et al since Wada et al teach that these are common optical sources and detectors for evaluating a cell to be sorted flowing through a channel network.

8. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diessel et al in view of Clark. For a teaching of Diessel et al, see previous paragraphs in this Office action. Diessel et al fail to teach that the magnetostrictive sorting actuator in the device for sorting cells is a magnetostrictive rod that can change length in response to a magnetic field.

Clark teaches of a magnetostrictive transducer used to control fluid flow through a channel. The transducer comprises a magnetostrictive rod 12 disposed within a fluid flow channel 10. The rod is initially in close fitment with a discharge port 14 to restrain the flow of fluids through the port 14. When a magnetic field is created around the assembly, the housing expands and the rod contracts, causing the rod to separate from close, seated fitment with the discharge port 14, thereby allowing flow through the port. See Figures 1a-1c, lines 37-68 in column 3 and lines 1-29 in column 4 of Clark.

Based upon the combination of Diessel et al and Clark, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a magnetostrictive rod, such as the one taught by Clark, as the magnetostrictive sorting actuator in the cell sorting device taught by Diessel et al since Clark teaches that a magnetostrictive rod located in a fluid flow channel can either allow or stop the flow of fluid in the channel depending upon its exposure to an external magnetic field, which is equivalent to the magnetostrictive narrowing or widening of the fluid flow channel taught by Diessel et al.

9. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diessel et al in view of Kamentsky et al. For a teaching of Diessel et al, see previous paragraphs in this Office action. Diessel et al fail to teach that the optical detection system for measuring cell parameters flowing through the device contains optical fibers for conveying light from a source into the main channel.

Kamentsky et al teach of a particle sorter, which comprises a stream of particles 29 flowing through a central channel. An optical detection system is located along the channel to measure cell parameters that consists of a light source 30 on one side of the channel and

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photoresponsive pick-up elements 42 and 44 located on the opposite side of the channel.

Kamentsky et al teach that fiber optics may be employed to carry light illumination from a lamp to the channel and from the channel to a photoelectric pick-up element. The cells are then sorted into one of two outlet channels 62 or 64. See Figure 1, lines 56-67 in column 2, lines 1-25 in column 3, lines 45-50 in column 5 and lines 43-54 in column 8 of Kamentsky et al.

Based upon a combination of Diessel et al and Kamentsky et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include optical fibers in the optical detection system of the cell sorter taught by Diessel et al since Diessel et al disclose that light guides are used in the optical detection system, and Kamentsky et al teach that optical fibers are a type of light guide to guide light from a source into a fluid flow channel for detecting cells in the fluid.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Spence et al, Wang et al, Gohde et al and Stiller who teach of different types of cell sorting devices.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 19, 2005

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